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STATE OF NEW MEXICO)
) ss.
COUNTY OF BERNALILLO)

I, Robert W. Becker, of 47 East Ridge, Edgewood, New Mexico 87015, being first duly sworn, state that:

1. I am of legal age.

2. I am familiar with both the German and English languages.

3. I have prepared the attached literal translation of the German text for the German Application Document Nr. 198 03 628.0 filed February 1, 1998.

4. I believe that to the best of my knowledge, the translation referred to in paragraph 3 above is a complete and true translation of the German text.

Robert W. Becker

Subscribed and sworn to before me this 20th day of March, 2003, by Robert W. Becker.

Notary Public

My commission expires:
7/23/06

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Device for Regeneration of Human or Animal Bone, in Particular for the Jawbone

The invention relates to a device for regeneration, repair and modeling of human and animal bones with any type of bone material, for example, on a synthetic basis, particularly, however, in the jaw area. Accordingly the device can be used in all areas of a human or animal skeleton, for repairing and modeling bone portions, as well as complicated fractures with defects, whereby the device is not limited to a certain bone shape.

The invention is based on the knowledge that the different materials employed for the regeneration of bone material, for example, a patient's own ground bone material and/or, for example Bio-Oss (trademark), are relatively pressure-sensitive and can therefore atrophy or be reabsorbed during the healing and building phase. Accordingly, in known regeneration methods of the human jaw, for example, atrophies and constrictions and bone loss cannot be avoided. The desired effect of regeneration being as complete as possible, especially in the vertical dimension, thus practically cannot be achieved.

The aforementioned and other known materials, which serve for regenerating and reconstructing bone – also included here are bone blocks – are referred to subsequently as bone replacement materials.

The invention is based essentially on the object of avoiding the aforementioned disadvantages of atrophy, that is, constrictions between the implant and all other bone deposits and repair locations, as well as respective contour changes.

For resolution of this object, according to the present invention, a device is provided that is characterized by a bending-resistant bar or strip for bridging of regenerating, repair, and modeling locations at the bone, which can be supported by two spaced apart implants. This bar or strip receives pressure forces and thereby reduces greatly a pressure loading of the bone replacement materials. In addition, the bar locally distributes occurring forces onto larger areas in order to thereby reduce specific pressure forces. At the same time, however, the bar also protects and stabilizes the associated implants. In addition, the bar offers the advantages of securing and optionally fastening the membranes that are used during this type of regeneration process, for example, for retaining connective tissues, in which the membranes are guided across the bar and supported on the bar.

Expediently, the bar includes two or more penetrations distributed over its length, preferably slotted holes, through which fastening elements, for example, pins or screws, are guided, which are secured or screwed into the implant. The slotted holes have the advantage that the bar can be secured at implants with non-uniform spacing between them.

While known implants for the dental jaw are provided with roughened surfaces, depressions, or penetrations, the present invention suggests pin-shaped, for example, cylindrical, implants that are polished on their exterior surface, and are thereby so smooth that in an implanted state, they can be rotated, when applying a force, about its longitudinal axis even after having been implanted for an extended time period. In addition, it is especially advantageous in this connection when the implants are provided with an outer thread. These implants are height-adjustable by rotation and, in the case of bone reconstruction that is to be carried out in stages, the

implants can be adjusted with respect to their relative vertical position by sequential steps of approximately 4 mm after an initial build-up phase of approximately nine months.

After the regeneration, the implants 4 can be removed or support elements for dental elements or the like or also other utilitarian elements can be provided.

Further details of the invention will be explained with reference to the drawings, in which the embodiments of the invention are represented. They show:

Fig. 1 a plan view of a longitudinal section of a bar that is suitable for regeneration of the jaw bone;

Fig. 2 the bar section according to Fig. 1 in a side view;

Fig. 3 a bar in plan view that is slightly different than the one shown in Fig. 1;

Fig. 4 the bar section according to Fig. 3 in a side view;

Fig. 5 an implant in an end view that can be used in connection with the bar of Figs. 1-4;

Fig. 6 a section along the line VI-VI of Fig. 3 together with an implant according to Fig. 5;

Fig. 7 a schematically represented longitudinal section of the regeneration area of a jaw bone to be reconstructed;

Fig. 8 shows a part section view of the fastening element for a bar.

The bar 1, which can be made of titanium, for example, or any other suitable material, has a substantially flat design with a large length extension. In cross section, the bar has centrally arranged penetrations in the form of round holes 2, preferably, however, slotted holes 3 extending in the longitudinal direction of the bar and distributed over its length. The slotted holes 3 provide for an improved

adaptability to imprecisely positioned implants 4. The bar or strip 1 has recesses 5 at both edges and at the underside, it is provided with transverse grooves 6. Such reductions 5, 6 in the cross-sectional shape make possible cutting in length and deformation of a bar 1 made with a longer section to a desired bar section. The transverse grooves 6 provide for easy cutting to length of the bar 1, while the notches 5 provide for bending deformation in order to adapt the bar 1 to the jaw curvature of the patient (predetermined bending locations).

The pin-shaped implants are likewise comprised of titanium, for example, or any other suitable material. Within the entire central shaft area, an outer thread 7 is provided. Otherwise, they are embodied so as to be very smooth or polished in order to be able to rotate the implant 4 in its operative position, that is, when implanted, about its longitudinal axis so that the implant 4 can be threaded in and out of the bone as necessary. For this purpose, the implant 4 can be formed at the upper end or head portion, such that it has a hexagon socket head in order to facilitate rotation. The implant 4 also has a longitudinal receiving bore 8 embodied as a blind bore open at the upper end. The bore 8 is provided for receiving a fastener 10 with a lens-shaped head 9, for example, shaped like a screw or a pin. The fastener 10, after removal of the bar 1, may optionally provide a cover for the implant 4, respectively, a closure element, in the area of the implant 4.

The diameter of the bores 2, respectively, the width of the slotted holes 3 is designed to match the diameter of the fastener 10, while the diameter of the implant 4 is slightly greater than the aforementioned diameter, respectively, the previously mentioned width. Accordingly, the bar 1, after having been cut to length, can be placed onto the implants 4, according to Fig. 6, and can be secured thereto with the

aid of the fasteners 10. Since the bores 2, respectively, slotted holes 3, widen at the upper side of the bar 1, the lens-shaped head 9 according to Fig. 6 is countersunk in order to prevent it from projecting.

As can be further seen in Fig. 6, the upper side 11 of the bar is curved, or convexly designed in order to prevent in its operative position perforations of the soft tissue, respectively, of the synthetic material possibly positioned there. The underside 22 of the bar 1 is designed substantially planar, but optionally can also be concave.

In Fig. 7, the bone to be regenerated or reshaped is indicated by reference numeral 13 and the reconstructed layer is indicated by reference numeral 14. The initial bone contour is indicated by reference numeral 15.

When one assumes that a plurality of implants 4 is arranged in the reconstructed area 14, but without the bar 1 and without the special design of the implants according to Fig. 5, and when employing a conventional free comb-shaped bone transplant, the resulting atrophy produces a contour according to the dashed line 16. When, instead, according to the present invention, a bar 1 is provided, pressure loading of the reconstructed layer 14 is avoided and the reconstructed layer remains intact. The bar 1 not only bridges the reconstructed material between the implants 4, it also stabilizes the implants 4.

The presence of the bar, however, also allows possibilities for other application in that a membrane 17, especially for protecting the reconstructed layer 14 or for separating and retaining the connective tissue, can be provided. The membrane 17 covers the bar 1 and can be attached thereto by the lens-shaped head

9, whereby the fasteners can penetrate the membrane 17 and clamp the membrane 17 between the bar 1 and the lens-shaped head 9.

After completion of the desired regeneration and/or apposition, the membrane 17 and the bar 1 are removed.

It should be noted that, as can be seen in Fig. 3, notches 5 must be positioned remote from the slotted holes 3 in order to prevent, during deformation of the straight bar 1 into the substantially U-shaped jaw shape, respectively, a curved shape of another bone, a width reduction of the slotted holes 3.

Further, it should also be noted that the represented mechanical connection between the bar 1 and the implant 4 is advantageous, and that, however, other connecting means can be used. It is important in this case that the implanted bar 1 in the region of its upper side 11 has a curvature, that is, is rounded and thus prevents perforations of the mucus membranes or other tissues or materials, and thus also of the membrane 17.

Finally, it should also be noted that the invention includes also bars 1, which already during manufacture have been shaped to the typical design of the bone to be treated, for example, for a jaw bone, the bar has a substantially U-shaped contour in a top view.

Although the present invention, respectively, provides a bar preferably for the bone regeneration of human jaws, it can also be used at any other location within the skeleton of a human or animal, for example, with fractures.

After the treatment, the bar 1 is removed. However, it is within the scope of the invention to leave the bar 1 at the treatment location.

The embodiment of Fig. 8 has a special feature in comparison to that of Fig. 5. In Fig. 8, there is also shown a fastener 10 for the bar 1 with an outer thread 20, but the fastener 10 has an upwardly open blind bore 21 with an inner thread 22, penetrating the head and a portion of the shaft of the fastener. The blind bore 21, after mounting of the bar 1 and providing penetrations in optional covers (mucous membrane), receives preferably threadable fastening devices for prostheses, bridges or other dental chewing aids and/or cosmetic devices and/or reconstructive devices positioned external to or above the skin. The attachment may be temporary or also permanent. This additional attachment function of the fastener 10 has the advantage that, for example, in reconstructive oral surgery the patient that generally has no teeth will be able to chew again. In any case, it is at least possible to realize cosmetic purposes. The fastening devices, which are not disclosed in any detail, can be of any desired type, and for example, may be conical pins; also it is not necessary that only threaded screws be used.

PATENT CLAIMS

1. Device for regeneration, repair and modeling of human or animal bone with bone replacement material, for example, on a synthetic basis, in particular, in the jaw area, characterized by at least two spaced part implants arranged on a bone to be machined, a bending-resistance bar (1) for bridging at least one regeneration, repair or modeling location on the bone.

2. Device according to claim 1, characterized in that the bar (1) is provided with two or more penetrations (2, 3) distributed over its length for mounting the bar (1) on the implants (4) that are preferably made from titanium.

3. Device according to claim 2, characterized in that the penetrations are slotted holes extending lengthwise in the longitudinal direction.

4. Device according to claim 1, characterized in that the bar (1) has an essentially flat cross section.

5. Device according to claim 1, characterized in that the upper side of the bar (1), when viewed in cross section, has a convex shape.

6. Device according to claim 1 or 2, characterized in that the bar has areas of reduced cross-sectional size defining the ending locations for bending the bar.

7. Device according to claim 6, characterized in that the bending locations are located at lateral edges of the bar remote from the penetrations or at an underside of the bar.

8. Device according to claim 6, characterized in that the bending locations are break-off locations.

9. Device according to claim 6, characterized in that the bending locations (6) are located on the underside of the bar.

10. Device according to claim 1, characterized in that the pin-shaped implants (5), for example, in view of roughening, depressions, or penetrations, are formed such that they are rotatable in operation about their longitudinal axes.

11. Device according to claim 10, characterized in that the implants (4) are provided with an outer thread (7) for vertical height adjustment.

12. Device according to claim 1, characterized in that the implants (4) in a head area have attachment elements (10) for a membrane (17) and/or the bar (1), whereby the attachment elements (10) penetrate the bar.

13. Device according to claim 12, characterized in that the attachment elements (10) are needle- or screw-type elements that are guidable into recesses (8, slotted holes) of the implants (4).

14. Device according to claim 1, characterized in that the implants (4) serve to hold the utilitarian elements, for example, teeth elements, after the regeneration, repair or modeling.

15. Device according to claim 12, characterized in that the head (9) of the attachment elements (10) can be lowered into the outer cross sectional area of the bar (1).

16. Device according to claim 1, characterized in that the bar (1) is designed to support a membrane or the periosteum of the bone, wherein the membrane or the periosteum retain the connective tissue and cover the reshaping location.

17. Device according to claim 1, characterized in that the underside of the bar is concave.

18. Device according to claim 1, characterized in that the fasteners (1) for the bar (10) associated with the implants (4) serve to secure permanently or temporarily prostheses, bridges or other reconstructive devices and/or cosmetic devices and/or reconstructive means lying externally to the skin.

19. Device according to claim 18, characterized in that the fasteners (10) embodied as screws or pins have longitudinal bores accessible from above that are provided with an inner thread.

20. Device according to claim19, characterized in that the longitudinal bores (21) are blind bores.

21. Bar according to one or more of the preceding claims.

22. Implantation according to one or more of the preceding claims.